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10/686,801	10/16/2003	Shibnath Ghosal	4822-129 US	7933

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EXAMINER	
HUYNH, CARLIC K	
ART UNIT	PAPER NUMBER
1612	
MAIL DATE	DELIVERY MODE
02/22/2008	PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	10/686,801	GHOSAL, SHIBNATH	
	Examiner	Art Unit	
	CARLIC K. HUYNH	1612	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE *3* MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *27 November 2007*.

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1,2,5-11,13-22 and 24-37* is/are pending in the application.

4a) Of the above claim(s) *28,29 and 35* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1,2,5-11,13-22,24-27,30-34,36 and 37* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date *22 January 2008*.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

Receipt of applicants' amendments and remarks filed on November 27, 2007 is acknowledged.

Status of the Claims

1. Claims 1-2, 5-11, 13-22, and 24-37 are pending in the application, with claims 3-4, 12, and 23 having been cancelled, in response to the non-final rejection submitted on February 20, 2007, and claims 28-29 and 35 having been withdrawn from consideration, in response to the non-final rejection submitted on February 20, 2007. Accordingly, claims 1-2, 5-11, 13-22, 24-27, 30-34, and 36-37 are being examined on the merits herein.

2. Claims 1-2, 5-11, 13-22, 24-27, 30-34, and 36-37 are drawn to a composition and thus intended use is not given any patentable weight.

The Obviousness-Type Double Patenting Rejections to claims 1, 5, 9-11, 13-16, 18, 20, 31, 33, and 36-37 as being unpatentable over claim 8 of Ghosal (US 6,440,436) have been withdrawn in view of Applicants' arguments.

The Obviousness-Type Double Patenting Rejections to claims 1, 5, 9-11, 13-16, 18, 20, 31, 33, and 36-37 as being unpatentable over claims 18, 46, 51, and 55 of copending Application Ghosal (US 2006/0062863 or 11/229871) have been withdrawn in view of Applicants' arguments.

Information Disclosure Statement

The Information Disclosure Statement submitted on January 22, 2008 is acknowledged.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

3. Claims 1-2, 5-11, 13-22, 24-27, 30-34, and 36-37 are rejected under 35 U.S.C. 103(a) as being unpatentable over Ghosal (US 6,362,167) in view of Ghosal (US 6,440,436), as evidenced by Pushpangadan et al. (US 2003/0185913), and in further view of Boynton et al. (US 5,087,623).

Ghosal (US 6,362,167) teaches extracts of the fruit of the *Emblica officinalis* plant and its administration to provide antioxidant activity to block free radical processes without pro-oxidant side reactions, optionally including an additional antioxidant (column 3, lines 59-63).

Ghosal (US 6,362,167) does not teach phenolic anti-oxidants from purified shilajit.

Ghosal (US 6,440,436) teaches a purified shilajit composition comprising oxygenated dibenzo-α-pyrone (DBP), its di- and/or tetramers, and their esters as well as carrier molecules which are low-to-medium molecular weight fulvic acids (column 2, lines 62-66; and column 3, lines 57-59). The molecular weight of the fulvic acids ranges from 700 to 2000 (column 5, lines 52-53). Pharmaceutical formulations of the purified shilajit composition are also taught (abstract).

As evidenced by Pushpangadan et al., herbal health compositions can be used to control blood sugar levels in patients with diabetes (page 2, paragraph [0014]). Pushpangadan et al. also disclose commercial herbal anti-diabetic products containing Shilajit and *Phyllanthus emblica* (pages 9-10, Table 1).

Hyperglycemia is defined as abnormally high concentrations of glucose in the circulating blood especially in patients with diabetes.

Thus, the extract from the fruit of the *Emblica officinalis* plant and purified shilajit can be used to treat hyperglycemia in patients with diabetes.

Neither Ghosal (US 6,362,167) nor Ghosal (US 6,440,436) teach the phenolic anti-oxidant complex with chromium.

Boynton et al. teach a treatment for controlling high blood serum glucose levels comprising administering chromic picolinate (abstract). The chromium is known to improve glucose tolerance (column 2, lines 19-20).

Boynton et al. also teach trivalent chromium in the amount of 200 μg of chromium or 12.5% chromium content (column 3, line 32 and column 7, lines 19-20). Additionally, the chromium tripicolinate is synthesized by combining picolinic acid and chromic chloride in deionized water, of which the final product (chromium picolinate) is air-dried (column 7, lines 3-13).

To a person of skill in the art at the time of the invention, it would have been obvious to employ the extracts of Ghosal (US 6,362,167) and Ghosal (US 6,440,436) as evidenced by Pushpangadan et al. to contain chromium because the chromic picolinate of Boynton et al. can be used to control high blood serum glucose levels and according to Pushpangadan et al. and

Boynton et al., both the extracts from *Phyllanthus emblica* fruit and purified shilajit and chromium are used to control high blood serum glucose levels.

The motivation to combine the extracts of Ghosal (US 6,362,167) and Ghosal (US 6,440,436) as evidenced by Pushpangadan et al. to the chromic picolinate compound of Boynton et al. is that the extracts from *Phyllanthus emblica* fruit and purified shilajit of Ghosal (US 6,362,167) and Ghosal (US 6,440,436) and the chromic picolinate compounds of Boynton et al. control high blood serum glucose levels.

Regarding chromium content in the complex, as recited in claims 7 and 26, it is noted that Boynton et al. teach providing chromium picolinate will yield a composition containing 12.5% chromium content, which closely meets the amount of chromium content set forth in claims 7 and 26. It is considered that one of ordinary skill in the art at the time the invention was made would have found it obvious to vary and/or optimize the amount of chromium picolinate provided in a composition, according to the guidance set forth in Boynton et al., to provide a composition having desired chromium content. It is noted that "[W]here the general conditions of a claim are disclosed in the prior art, it is not inventive to discover the optimum or workable ranges by routine experimentation." *In re Aller*, 220 F.2d 454, 456, 105 USPQ 223, 235 (CCPA 1955).

Regarding chromium content in the complex, as recited in claims 9, 19, and 27, it is noted that Ghosal teaches providing fulvic acids in a composition with Mw 700-2000, which closely meets the amount of chromium content set forth in claims 9, 19, and 27. It is considered that one of ordinary skill in the art at the time the invention was made would have found it obvious to vary and/or optimize the Mw of fulvic acids provided in a composition, according to the

guidance set forth in Ghosal, to provide a composition having desired Mw of fulvic acids. It is noted that "[W]here the general conditions of a claim are disclosed in the prior art, it is not inventive to discover the optimum or workable ranges by routine experimentation." *In re Aller*, 220 F.2d 454, 456, 105 USPQ 223, 235 (CCPA 1955).

Regarding *Phyllanthus emblica* as recited in the instant claim 13, it is disclosed in the instant specification that *Emblica officinalis* is synonymous with *Phyllanthus emblica* (page 8, paragraph 3).

Response to Arguments

4. Applicants' arguments, see "Amendment-After Non-Final Rejection" filed on September 5, 2007, with respect to "Rejections under 35 U.S.C. § 103" to claims 1-2, 5-11, 13-22, 24-27, 30-34, and 36-37 has been fully considered and are not persuasive.

Applicants argue Pushpangadan et al. (US 2003/0185913) does not teach herbal health compositions containing either Shilajit or *Phyllanthus emblica*.

In response, Examiner points out that Pushpangadan et al. was used to show that herbal health compositions can be used to control blood sugar levels in patients with diabetes and that commercial herbal anti-diabetic products containing Shilajit and *Phyllanthus emblica* are available (page 2, paragraph [0014]; and pages 9-10, Table 1).

Applicants further argue that the invention is directed to a composition for treating diabetes or glucose intolerance comprising administering a safe and effective phenolic-chromium complex that prevents the chromium from being systemically converted from Chromium (III) to Chromium (IV). Applicant argues that the invention is not merely a predictable combination of

elements to control high blood serum glucose levels as per Examiner's conclusions. Applicant also argues that the amount of Chromium disclosed in Boynton et al. cannot be adjusted through routine experimentation.

In response, Examiner notes that Boynton et al. (US 5,087,623) teaches chromium in the amount of 200 μg or 12.5%. Examiner further notes that the phenolic antioxidant-chromium complex is formed by reacting the phenolic antioxidant with chromium. It would be obvious to combine the chromium from Boynton et al. with the phenolic antioxidant from Ghosal (US 6,362,167) and Ghosal (US 6,440,436) and generate the phenolic antioxidant-chromium complex of the instant invention. Regarding adjusting the chromium content in Boynton et al., Examiner maintains *in re Aller* because the skilled artisan can adjust the amount of chromium disclosed in Boynton et al. to the amount of chromium need in the instant phenolic antioxidant-chromium complex.

Thus, the Rejections under 35 U.S.C. § 103 to claims 1-2, 5-11, 13-22, 24-27, 30-34, and 36-37 have been maintained.

Double Patenting

Obviousness-Type

The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. A nonstatutory obviousness-type double patenting rejection is appropriate where the conflicting claims are not identical, but at least one examined application claim is not patentably distinct from the reference claim(s) because the examined application claim is either anticipated by, or would have been obvious over, the reference claim(s). See, e.g., *In re Berg*, 140 F.3d 1428, 46 USPQ2d 1226 (Fed. Cir. 1998); *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re*

Vogel, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) or 1.321(d) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent either is shown to be commonly owned with this application, or claims an invention made as a result of activities undertaken within the scope of a joint research agreement.

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

5. Claims 1, 5, 9-11, 13-16, 18, 20, 31, 33, and 36-37 are rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claim 1 of Ghosal (US 6,440,436) and claim 1 of Ghosal (US 6,869,612).

The conflicting claims are not patentably distinct. Claim 1 of Ghosal (US 6,440,436) and claim 1 of Ghosal (US 6,869,612) are directed to the purified shilajit composition, which consists essentially of oxygenated dibenzo-α-pyrones in metal ion conjugate forms. Conjugates are known in the art to be joined or paired. A complex is known in the art as a combination of two or more compounds without covalent binding. As such, a complex can be view as a specific type of conjugate. The purified shilajit composition, which consists essentially of oxygenated dibenzo-α-pyrones in metal ion conjugate forms is the phenolic antioxidant-chromium complex of the instant claims.

Thus the oxygenated dibenzo-α-pyrones in metal ion conjugate forms of Ghosal (US 6,440,436) and Ghosal (US 6,869,612) and the phenolic antioxidant-chromium complex of the instant application are not patentably distinct.

Response to Arguments

6. Applicants' arguments, see "Remarks" filed on November 27, 2007, with respect to "Obviousness-Type Double Patenting" to claims 1, 5, 9-11, 13-16, 18, 20, 31, 33, and 36-37 have been fully considered and are not found persuasive. Applicants argue that no explanation as to why the extract of Shilajit is the same as the extract of the fruit of the *Emblica officinalis*. In response, Examiner points that the extracted product, oxygenated dibenzo-α-pyrones (DBPs), is the same regardless of the source and as such, the oxygenated dibenzo-α-pyrones (DBPs) from Shilajit is the same as the oxygenated dibenzo-α-pyrones (DBPs) from *Emblica officinalis*. Thus the Obviousness-Type Double Patenting Rejection between instant claims 1, 5, 9-11, 13-16, 18, 20, 31, 33, and 36-37 and claim 1 of Ghosal (US 6,440,436) and claim 1 of Ghosal (US 6,869,612) has been maintained.

Conclusion

7. No claims are allowable.

8. **THIS ACTION IS MADE FINAL.** Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event,

however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Carlic K. Huynh whose telephone number is 571-272-5574. The examiner can normally be reached on Monday to Friday, 8:30AM to 5:00PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Frederick Krass can be reached on 571-272-0580. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Gollamudi S Kishore, Ph.D/
Primary Examiner, Art Unit 1612

ckh